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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|---|---|---|---|

| EXAMINER |
|---|

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

**DATE MAILED:**

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 9/3/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days ~~month(s),~~ or ~~thirty days,~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response ~~will cause~~ the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☑ Claim(s) 1-47 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☑ Claim(s) 1-47 are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**--SEE OFFICE ACTION ON THE FOLLOWING PAGES--**

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Paula Hutzell@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. In view of the inadvertent omission of claims 42-47 on page 71 of the specification in the previous restriction requirement, the restriction requirement filed May 27, 1998 (Paper No. 7) is vacated.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

**Group I.** Claims 1-25 are drawn to an isolated nucleic acid molecule comprising a polynucleotide which specifically hybridizes to a sequence, classified in Class 536, subclass 23.1.

**Group II.** Claims 26-41 are drawn to a method of screening for neoplastic cells and for identifying mutations comprising contacting a nucleic acid with a polynucleotide probe, classified in Class 435, subclass 6.

**Group III.** Claims 42-43 and 45-47 are drawn to a method of screening for neoplastic cells comprising contacting a polypeptide antigen encoded by a

specified polynucleotide sequence with an antibody that specifically binds to said antigen, classified in Class 435, subclass 7.1.

**Group IV.** Claim 44 is drawn to a method of inhibiting the pathological proliferation of cancer cells comprising inhibiting the activity of a gene product having a subsequence which hybridizes under stringent conditions to a recited sequence , classified in Class 242, subclass 130.1 and Class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II-IV are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions I and II/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid product as claimed can be used in a materially different process such as expressing the protein encoded by the polynucleotide.

The inventions of Groups I and III are not at all related because the nucleic acid of Group I is not used in any of the methods of Group III.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising polynucleotide probes with different sequences, structures and functions that hybridize to different nucleic acid sequences wherein the probe sequences are selected from the group consisting of (a) SEQ ID NO: 2 (claims 1 and 2-3), (b) SEQ ID NO: 3 (claims 1 and 4-5), (c) SEQ ID NO:4 (claims 1 and 6-7), (d) SEQ ID NO: 5 (claims 1 and 8-9), (e) SEQ ID NO: 6 (claims 1 and 10-11), (f) SEQ ID NO: 7 (claims 1 and 12-13), (g) SEQ ID NO: 8 (claims 1 and 14-15, (h) SEQ ID NO: 9 (claims 1 and 16-17), (I) SEQ ID NO: 10 (claims 1 and 18-19, (j) SEQ ID NO: 12 (claims 1 and 20-21), (k) SEQ ID NO: 13 (claims 1 and 22-23).

5. Group II is further subject to election of a single disclosed species.

Claim 26 is generic to a plurality of disclosed patentably distinct species comprising polynucleotide probes which hybridize to target polynucleotide sequences with different sequences, structures and functions that hybridize to different nucleic acid sequences wherein the probe sequences are selected from the group consisting of (a) SEQ ID NO: 1 (claims 26 and 29), (b) SEQ ID NO: 2 (claims 26 and 30), (c) SEQ ID NO:3 (claims 26 and 31), (d) SEQ ID NO: 4 (claims 26 and 32), (e) SEQ ID NO: 5 (claims 26 and 33), (f) SEQ ID NO: 6 (claims 26 and 34), (g) SEQ ID NO: 7 (claims 26 and 35), (h) SEQ ID NO: 8 (claims 26 and 36), (I) SEQ ID NO: 9 (claims 26 and 37), (j) SEQ ID NO: 10 (claims 26 and 38), (k)

SEQ ID NO: 12 (claims 26 and 39), (l) SEQ ID NO: 13 (claims 26 and 40). Claim 41 will be examined as it is drawn to the elected species.

6. Group III is further subject to election of a single disclosed species.

Claim 42 is generic to a plurality of disclosed patentably distinct species comprising antibodies that specifically bind to polypeptide antigens which are encoded by different polynucleotide sequences, thus the antigens are proteins with different sequences, structures and functions and therefore the claimed antibodies would have different structures because they would bind to different epitopes wherein the coding polynucleotide sequences are selected from the group consisting of (a) SEQ ID NO: 1, (b) SEQ ID NO: 2, (c) SEQ ID NO:3, (d) SEQ ID NO: 4, (e) SEQ ID NO: 5, (f) SEQ ID NO: 6, (g) SEQ ID NO: 7, (h) SEQ ID NO: 8, (I) SEQ ID NO: 9, (j) SEQ ID NO: 10, (k) SEQ ID NO: 12, (l) SEQ ID NO: 13, (m) polynucleotide encoding ZABC1, (n) polynucleotide encoding 1b1. Applicant is requested to identify the polynucleotide sequence that encodes ZABC1 protein and the polynucleotide sequence which encodes 1b1 protein. If these proteins are encoded by any of the sequences identified with SEQ ID NOs, they will be examined as they are drawn to the elected species.

7. Group IV is further subject to election of a single disclosed species.

Claim 44 is generic to a plurality of disclosed patentably distinct species comprising molecules that inhibit the activity of gene products of an endogenous gene having a subsequence which hybridizes under stringent conditions to a polynucleotide sequence said inhibitors would be inhibiting gene products with different structures and functions and therefore would themselves have different

structures and functions from each other, wherein the polynucleotide sequences are selected from the group consisting of (a) SEQ ID NO: 1, (b) SEQ ID NO: 2, (c) SEQ ID NO:3, (d) SEQ ID NO: 4, (e) SEQ ID NO: 5, (f) SEQ ID NO: 6, (g) SEQ ID NO: 7, (h) SEQ ID NO: 8, (I) SEQ ID NO: 9, (j) SEQ ID NO: 10, (k) SEQ ID NO: 12, (l) SEQ ID NO: 13, all of claim 44.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

November 16, 1998